

Remarks

Claims 1-9 and 13-28 are currently pending in this application. In the Office Action mailed June 25, 2007, claims 1-12 were rejected. Applicants have amended claim 1, canceled claims 10-12, and added new claims 13-28. No new matter has been added. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

Claim Rejections – 35 USC § 102(e)

A. Marino

Claims 1-3 and 5-8 were rejected under 35 USC § 102(e) as being anticipated by US Patent Application No. 2002/0007129 to Marino (“Marino”). Applicants respectfully traverse these rejections as follows.

In order to reject a claim for anticipation under 35 USC § 102, it must be shown that each and every element of the claim can be found in a single reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1, as amended, describes a system for performing surgical procedures and assessments. The system comprises a surgical accessory having at least one stimulation electrode and (a processing system having at least one of computer programming software, firmware and hardware pre-programmed to incorporate at least two pre-selected threshold ranges, and capable of stimulating said at least one stimulation electrode on a surgical accessory with an electrical stimulation signal, measuring the response of nerves depolarized by said stimulation signal, automatically determining a stimulation threshold of said nerves by automatically adjusting said stimulation signal by variable increments, and communicating to a user which range of said at least two pre-selected ranges that said stimulation threshold lies to indicate at least one of nerve proximity-and pedicle integrity.

The amendments to claim 1 are made to define more particularly the subject matter sought to be patented. The amendments are made without prejudice to pursue the original subject matter further, for example, in a continuation application.

As expressed in the amended claim 1, the present system includes a processing system that determines a stimulation threshold and then determines where the stimulation threshold lies in range of threshold values that are predetermined to be indicative of at least one of nerve proximity and pedicle integrity.

The Marino reference teaches a system for determining nerve status and relative movement, including a stimulation electrode and a processing unit. However, Marino fails to describe a processing unit that indicates at least one of nerve proximity and pedicle integrity by **determining where a stimulation threshold lies within at least two pre-selected threshold ranges**. Instead, to assess relative nerve movement, Marino requires inducing at least a first selected nerve response (step 108) and a second selected nerve response (step 114) with the proximity electrode. Thereafter, the stimulation current levels used to induce the first and second responses are compared to determine whether changes have occurred during the time interval between the first stimulation and the second stimulation. (*Para. [0031]-[0033]*). By contrast, with the presently claimed system only a single stimulation threshold needs to be determined in order to determine at least one of nerve proximity or pedicle integrity.

Because the Marino reference is silent as to at least one element found in amended claim 1, it is respectfully requested that the anticipation rejection under 35 USC § 102(e) be withdrawn for each of claims 1-3 and 5-8. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby earnestly solicited. Furthermore, claims 2-3 and 5-8, being dependent upon and further limiting independent claim 1, should be deemed allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional features they contain.

Claim Rejections - 35 USC § 103(a)**A. Marino in view of Zucherman**

In Paragraph 4 of the Office Action, claim 4 was rejected under 35 USC § 103(a) as being obvious over Marino in view of US Patent 6,926,728 to Zucherman et al. ("Zucherman"). Applicants respectfully traverse this rejection as follows.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations.

Claim 4 is dependent upon and further limiting of claim 1. As discussed above, Marino does not teach all of the claimed limitations of claim 1. Notably, Marino fails to disclose a processing unit that indicates at least one of nerve proximity and pedicle integrity by determining where a stimulation threshold lies within at least two pre-selected threshold ranges. Zucherman does not fill this void left by Marino. Zucherman discloses a dilator system for gradually expanding an opening in body tissue. Nowhere in Zucherman is there discussion or suggestion of indicating at least one of pedicle integrity and nerve proximity by determining where a stimulation threshold lies within at least two pre-selected threshold ranges. The Applicants thus respectfully submit that the Marino and Zucherman references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 1, let alone the further limitations contained in claim 4. It is therefore respectfully requested that the rejection of claim 4 in Paragraph 4 of the Office Action be withdrawn in favor of an indication of allowability.

B. Marino in view of Prass

In the paragraph 5 of the Office Action, claim 9 was rejected under 35 USC § 103(a) as obvious over Marino in view of US Patent 6,292,701 to Prass et al. ("Prass"). Applicant respectfully traverses this rejection as follows.

Claim 9 is dependent upon and further limiting of independent claim 1. As discussed above, Marino does not teach all of the claimed limitations of claim 1. Again, Marino does not teach a processing unit that indicates at least one of nerve proximity and pedicle integrity by determining the position of a stimulation threshold within a range of predetermined threshold values. Prass fails to remedy the deficiencies left by the teaching of Marino. Prass does disclose a stimulation probe equipped with an electrode that may be used with a nerve monitoring system. However, there is no discussion in Prass of using the stimulus probe to determine at least one of pedicle integrity and nerve proximity, by determining the position of a stimulation threshold within a range of predetermined threshold values. The Applicants thus respectfully submit that the Marino and Prass references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 1. Claim 9 being dependent upon and further limiting independent claim 1, should also be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional limitations it contains. The Applicants thus respectfully request that the rejection of claim 9 in Paragraph 5 of the Office Action be withdrawn in favor of an indication of allowability.

C. Marino in view of Foley

In Paragraph 6 of the Office Action, claims 10 and 11 were rejected under 35 USC § 103(a) as obvious over Marino in view of US Patent 6,425,859 to Foley et al. ("Foley"). Though Applicants do not necessarily agree with the rejections, claims 10 and 11 have been canceled through this amendment such that the rejections are now moot.

D. Marino in view of Foley in view of Loubster

In Paragraph 7 of the Office Action, claim 13 were rejected under 35 USC § 103(a) as obvious over Marino in view of Foley and further in view of US Patent Application No. 2001/0039949 to Loubser. Though Applicants do not necessarily agree with the rejection, claim 12 has been canceled through this amendment such that the rejection is now moot.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
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